JUN 12 2007

14.0 510(k) Safety Summary K052936

A. Name of Device

Trade Name:	Thermage ThermaCool™ System
Common Name:	Electrosurgical Unit and Accessories
Classification Name:	Device, Electrosurgical Cutting and Coagulation and Accessories (21 CFR 878.4400)
Contact Person:	Pamela M. Buckman, RN, MS Vice President of Regulatory/Clinical Affairs

B. Predicate Devices

The predicate devices for the ThermaCool System for Eyelid Indication that is the subject of this 510(k) are:

Predicate	Premarket Notification
ThermaCool System	K043042, et al.
Lumenis Family of UltraPulse SurgiTouch CO, Surgical Lasers	K030147

K052936

C. Device Description

The Thermage ThermaCool System consists of the following components:

- ThermaCool System
- Handpiece Assembly (consisting of Handpiece and Treatment Tip)
- Accessories: Coolant Canister, Coupling Fluid, Return Pad and Skin Marking Paper
- Accessory cables and tubing
- Optional footswitch component

D. Indication for Use

The Thermage ThermaCool System for the new indication is: Non-invasive treatment of periorbital wrinkles and rhytids including the upper and lower eyelids.

E. Technical characteristics

The technological characteristics of the Thermage ThermaCool System for Eyelid Indications are identical to the cleared system. The required eye-shield is a commercially available device and is not the subject of this 510(k).

F. Summary

By virtue of design, principle of operation, materials and intended use, the Thermage ThermaCool System for Eyelid Indication is substantially equivalent to referenced devices currently cleared for marketing in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Thermage, Inc.
% Ms. Pamela M. Buckman, MSN
VP, Clinical/Regulatory
25881 Industrial Boulevard
Hayward, California 94545-2991

JUN 12 2007

Re: K052936
Trade/Device Name: Thermage ThermaCool System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: March 13, 2007
Received: March 14, 2007

Dear Ms. Buckman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

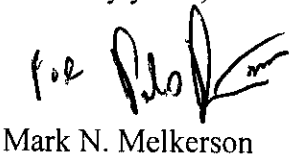
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.0 Indications for Use Statement

K052936

510(k) NUMBER (IF KNOWN): Not Known

DEVICE NAME: Thermage ThermaCool System

INDICATIONS FOR USE:

The Thermage ThermaCool System is indicated for use in:

- Dermatologic and general surgical procedures for electro coagulation and hemostasis,
- Non-invasive treatment of periorbital wrinkles and rhytids including the upper and lower eyelids
- Non-invasive treatment of facial wrinkles and rhytids

(Division Sign-Off)
Division of General, Restorati
and Neurological Devices

510(k) Number K052936

Prescription Use	X	OR	Over-The-Counter-Use	

(Per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)